N THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

STEINER, Mitchell S. et al.

Examiner:

Fubara, Blessing M

Serial No.:

10/747,686

Group Art Unit:

1615

Filed:

December 30, 2003

Title:

A METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER

Mail Stop Amendment Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO-1449:

- 1. Issting documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents, and/or United States patent applications, and/or United States patent application publications are not included in this information disclosure statement; and/or
- 2. Isting documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. 10/611,056, filed July 2, 2003 which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
- 3. A listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;
- 4. Illisting other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a count grant/2 for the religion, 50 3555 py 10747686 which is included with this information disclosure statents 1886 189.08 DA

APPLICANTS: SERIAL NO.:

STEINER, Mitchell S. et al. <u>+9761+,856</u> | 0/747, 486

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The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

I)		Within three (3) months of filing the subject Application or er	try of the subject
App	ication	into the national stage or before mailing of the first Office Action	on the merits of
the s	subject	Application or a request for continued examination thereof,	whichever event
occu	rs last p	ursuant to of 37 C.F.R §1.97 (b); or	•

- II) After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;
 - the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

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2. The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of \$180.00 under 37 C.F.R §1.17 (p) to Deposit Account 50-3355.

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Daposit Account No. 50-3355.

Respectfully submitted,

Mark S. Cohen

Attorney for Applicants Registration No. 42,425

Dated: July 19, 2006

PEARL COHEN ZEDEK LATZER LLP 1500 Broadway, 12th Floor New York, NY 10036 Phone: (646) 878-0800

and

Fax: (646) 878-0801

Sheet

PTO/SB/08A (10-96)
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P-2769-US9

Complete if Known Substitute for form 1449A/PTO 10/747,686 **Application Number** INFORMATION DISCLOSURE Filing Date **December 30, 2003** STATEMENT BY APPLICANT STEINER, Mitchell S. **First Named Inventor** Group Art Unit 1615 (use as many sheets as necessary) Fubara, Blessing M **Examiner Name**

Attorney Docket Number

			<u>U.</u>	S. PATENT DOCUMENTS		
		U.S. Pater	nt Document	Name of Patentee or Applicant	Date of Publication of	Pages, Columns, Lines Where Relevant
Examiner Initials*	Cite No. 1	Number	Kind Code ² (if known)	of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear
	Α	4,990,538		Harris et al.	February 5, 91	
	В	5,788,964		Baral et al.	August 4, 98	
	С	5,650,425		Biegnon et al.	July 22, 97	
	D	4,696,949		Toivola et al.	Sept 29, 87	
	E	5,491,173		Toivola et al.	Feb. 13, 1996	
	F	5,571,534		Jalonen et al.	Nov. 5, 1996	
	G	5,605,700		DeGregorio et al.	Feb. 25, 1997	
	Н	5,595,722		Grainger et al.	Jan. 21, 1997	
	ı	5,599,844		Grainger et al.	Feb. 4, 1997	
	J	5,629,007		Audia et al.	May 13, 1997	
	K	5,635,197		Audia et al.	June 3, 1997	
	L	5,595,985		Labrie	Jan. 21, 1997	
	ļ	3,373,983		LAUTE	Jul. 21, 1997	

			FORE	IGN PATENT DOCUME	ENTS		
Examiner Initials*	Cite No. 1		gnPatent Document Kind Code ⁵ Number ⁴ (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	76
	М	wo	98/58634	DEGREGORIO, et al	December 30, 98		
	N	ЕР	415 623 A2	Harris et al	March 6, 1991		
	0	EP	616 529 BI	·	September 28, 94		
	Р	EPC	095875	·	Dec 7, 1995		
	Q	wo	95/26720	Biegon et al	Oct 12, 1995		
	R	wo	0008001	Huebner, et al	Feb 17, 2000		

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Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

	Substitute	for form	1449A/PTO	Complete if Known		
			•	Application Number	10/747,686	
INF	ORMA	TION	DISCLOSURE	Filing Date	December 30, 2003	
STATEMENT BY APPLICANT		First Named Inventor	STEINER, Mitchell S.			
				Group Art Unit	1615	
((use as ma	any she	ets as necessary)	Examiner Name	Fubara, Blessing M	
Sheet	2	of	10	Attorney Docket Number	P-2769-US9	

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	s	4,329,364		Neri et al.	May 11, 1982	
	T	4,474,813		Neri et al.	Oct. 2, 1984	
	υ	6,080,877		Swindell et al	June, 2000	
	V	6,265,448		Steiner et al	July 24, 2001	
	W	6,410,043		Steiner et al	June 25, 2002	
	Х	6,632,447		Steiner et al	Oct 14, 2003	
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	AA	6,413,535		Steiner et al	July 2, 2002	
	AB	4,996,225		Toivola et al	Feb 26, 1991	
	AC	5,811,120		Gibson et al	Sept 22, 1998	
	AD	5,972,383		Gibson et al	Oct 26, 1999	
	AE	4,418,068	,	Jones	Nov 29, 1983	

			F	ORE	IGN PATENT DOCUME	ENTS		
Examiner Initials*	Cite No. 1		gnPatent Docur Number⁴ Kind (if knd		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Tf
	AF	wo	94/12162	T	Warri et al	June 9, 1994	Figures Appear	
	AG	wo	99/56739		Steiner et al	November 11, 1999		
	AH	wo	00/47214		Healey et al	August 17, 2000		
	AI	wo	96/09046		Audia et al	March 28, 1996		
	AJ	EP ·	0 670 162		Gibson et al	Sept 6, 1995		

Examiner	·	Date	
Signature		Considered	

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STA	ATEME	NT B	Y APPLICANT	First Named Inventor	STEINER, Mitchell S.	
				Group Art Unit	1615	
(1	use as ma	any shee	ets as necessary)	Examiner Name	Fubara, Blessing M	
Sheet	3	of	10	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	AK	Brawley et al., "Chemoprevention of Prostate Cancer" in Urology, 1994, Vol. 43, No. 5.	
		Christian Rohlff et al. "Prostate Cancer Cell Growth Inhibition by Tamoxifen Is Associated With Inhibition of Protein Linase C and Induction of p21" The Prostate 37:51-59 (1998) ©1998 Wiley-Liss, Inc	
	AM	Gershanovich et al., " A Phase III Comparison of Two Toremifene Doses to Tamoxifen in Postmenopausal Women with Advanced Breast Cancer", Breast Cancer Research and Treatment 45, 1997, Pages 251-262.	
	AN	Gingrich et al., "Androgen-independent Prostate Cancer Progression in the TRAMP Model", in Cancer Research 57, November 1, 1997, pages 4687-4691.	,
	AO	Gingrich et al., "Metastatic Prostrate Cancer in a Transgenic Mouse", in Cancer Research 56, September 15, 1996, pages 4096-4102.	
	AP	Gingrich et al., "Pathalogic Progression of Autochthonous Prostate Cancer in the TRAMP Model", Prostate Cancer and Prostatic Diseases, 1999, 2, Pages 70-75.	
	AQ	Greenwald "Expanding Horizons in Breast and Prostate Cancer Prevention and Early Detection", in J. Cancer Education, 1993, Vol. 8, No. 2, pages 91-107.	
	AR	Kelloff et al., "Introductory Remarks: Development of Chemopreventive Agents for Prostate Cancer" in Journal of Cellular Biochemistry, 1992, Supplement 16H: 1-8.	
	AS	Lucia et al., "Chemopreventive Activity of Tamoxifen, N-(4-Hydroxyphenyl)retinamide, and the Vitamin D Analogue Ro24-553 1 for Androgen-promoted Carcinomas of the Rat Seminal Vesicle and Prostate" in Cancer Research, 1995, vol. 55, pages 5621-5627.	
	АТ	Martel Celine et al. "Binding Characteristics of Novel Nonsteroidal Antestrogens to the Rat Uterine Estrogen Receptors", Pergamon, J. Steroid Biochem. Molec. Bio. Vol 64, No. 3-4, pp. 199-205, 1998.	
	AU	Nevalanine et al. "Hormone Regulation of Human Prostate in Organ Culture" Cancer Ress, vol. 53, no. 21, 1993, pages 5199-5207, XO002117653.	
	AV	Potter et al., "A Mechanistic Hypothesis for DNA Adduct Formation By Tamoxifen Following Hepatic Oxidative Metabolism" in Carcinogenesis, 1994, Vol. 15, No. 3, pages 439-442.	
	AW	Richard Gams, MD "Phase III Trials of Toremifene vs Tamoxifen" Oncology Volume 11, Number 5, Supplement 4, May 1997	
	AX	Schneider Martin R. et al. "Nonsteroidal Antiestrogens and Partial Estrogens with Prostatic Tumor Inhibiting Activity", Cancer Research Clinical Oncology Springer-Verlag 1986, J Cancer Res Clin Oncol (1986) 112: 258-265, p. 258-265,	
	AY	Valavaara Ritva, MD, PhD "Reliability of Estrogen Receptors in Predicting Response To Antiestrogens", Oncology, Volume 11 Number 5 Supplement No. 4 p. 14-18.	

Examiner Date Considered				
Signature	Examiner		Date	
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	AZ	Black et al. "Uterine Bioassay of Tamoxifen, Trioxifene and a New Estrogen Antogonist (LY117018) in Rats and Mice" in Life Sciences, 1980, Vol. 26, pp. 1453-1458	
	ВА	Greenwald et al. "Breast Cancer Prevention and Early Detection", pages 93-106.	
	BB	Hayes et al. "Randomized Comparison of Tamoxifen and Two Separate Doses of	+
		Toremifenein Postmenopausal Patients with Metastatic Breast Cancer", Journal of Clinical Oncology, Vol. 13, No. 10, 1995, pages 2556-2566.	
		Hietanen T "Open Phase II Study of High-Dose Toremifene as First-Line Therapy for Advanced Breast Cancer" in Oncology - May 1997; 11(5 Suppl 4): 37-40.	
	BD	Jordan VC "Toremifene As An Anticancer Agent", Cancer Invest 1990; 8(2) 271	
	BE.	Karlsson S. et al. "A Two-Year Dietary Carcinogenicity Study Of The Antiestrogen Toremifene In Sprague-Dawley Rats" Drug Chem Toxicol 1996 Nov; 19(4): 245-66.	
	BF	Moon RC et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Res 1994 May-June; 14(3A): 889-93.	
	BG	Moore et al. "Regulation of Cytoplasmic Dihydrotestosterone Binding in Dog Prostate by 17β-Estadiol", in J. Clin. Invest. © The American Society for Clinical Investigation, Inc., Vol. 63 March 1979, pages 351-357.	
	вн	Neubauer et al., "Endocrine and Antiprostatic Effects of Raloxifene (LY156758) in the Male Rat", The Prostate 23, 1993, pages 245-262.	
	ВІ	Perry "High Dose Toremifene for Estrogen and Progesterone Receptor Negative Metastatic Breast Cancer: a Phase II Trial of the Cancer and Leukemia Group B (CALGB)", in Breast Cancer Res Treat - 1995; 26(1): 25-40	
	BJ	Pollard, "Prevention of Prostate-Related Cancers in Lobund-Wistar Rats", The Prostate 39, 1999, pages 305-309.	
	вк	Powles TJ "Status Of Antiestrogen Breast Cancer Prevention Trials" Oncology (Huntingt) 1998 Mar; 12(3 Suppl 5): 28-31.	
	BL	Pyrhönen et al., "Comparison of Toremifene and Tamoxifen in Postmenopausal Patients with Advanced Breast Cancer: a Randomized Double-blind, the 'Nordic' Phase III Study", British Journal of Cancer, 1997, 76(2), pages 270-277.	
	вм	Shenfeld et al. "Androgen Deprivation Therapy", Chapter 37, Section III/Prostate Cancer, pages 467-477	
	BN	Shirai et al. "Effects of Testosterone, Dihydrotestosterone and Estrogen on 3,2'-Dimethyl-4-Aminobiphenyl-Induced Rat Prostate Carcinogenesis" in Int. J Cancer: 57, 224-228 (1994)	
	во	Simard et al., "Keoxifene Shows Pure Antiestrogenic Activity in Pituitary Gonadotrophs", Molecular and Cellular Endocrinology 39, 1985, pages 141-144.	

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Sheet	5	of	10	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	BP	"Chemoprevention Of Prostate Cancer: Guidelines For Possible Intervention Strategies", Journal of Cellular Biochemistry, Supplement 16H:140-145 (1992).	
	BQ	Awoniyi Caleb A. et al. "Neonatal Exposure To Coumestrol, A Phystoestrogen, Does Not Alter Spermatogenic Potential In Rats", Endocrine, vol. 7, no. 3, 337-341, December 1997.	
	BR	Bergan RC et al. "A Phase II Study Of High-Dose Tamoxifen In Patients With Hormone-Refractory Prostate Cancer." Clin Cancer Res 1999 Sep; 5(9): 2366-73.	
	BS	Brandes LJ et al. "Salutary Clinical Response Of Prostate Cancer To Antiandrogen Withdrawal: Assessment Of Flutamide In An In Vitro Paragdigm Predictive Of Tumor Growth Enbancement", Clin Cancer Res 1997 Aug; 3(8): 1357-61.	
	ВТ	Chang William Y et al. "Estrogen Receptor-β: Implications For The Prostate Gland" The Prostate 40:115-124 (1999)	
	BU	Foekens JA et al. "Expression Of Prostate-Specific Antigen (PSA) Correlates With Poor Response To Tamoxifen Therapy In Recurrent Breast Cancer", Br J Cancer 1999 Feb; 79(5-6): 888-94.	
	BV	Hempstock J. et al. "Growth Inhibition Of Prostate Cell Lines In Vitro By Phyto- Oestrogens", British Journal Of Urology (1998). 82. 560-563.	
	BW	Lippman SM et al. "Cancer Chemoprevention", J Clin Oncol 1994 Apr; 12(4):851-73.	
	вх	Miyata E et al. "Effects Of Tamoxifen, An Antiestrogen, On Rat Prostate Carcinogenesis by 3,2'-Dimethyl-4-Aminobiphenyl And Testerone Do Not Support An Estrogen Role In Testerone Promotion", Prostate 1997 Apr 1;31(1)9-13.	
	BY	Nevalainen MT et al. "Expression and Hormone Regulation Of Prolactin Receptors in Rat Dorsal and Lateral Prostate", Endocrinology 1996 Jul; 137(7): 3078-88.	
	BZ	Pienta KJ et al. "A Phase II Evaluation Of Oral Tamoxifen And Intermittent Intravenous Vinblastine In Hormone-Refractory Adenocarcinoma Of The Prostate"., Am J Clin Oncol 1996 Oct; 19(5):500-3.	
	CA	Pienta KJ et al. "Inhibition Of Prostate Cancer Growth By Vinblastine And Tamoxifen", Prostate 1995 May; 26(5): 270-4.	
	СВ	Prins Gail S. et al, "Neonatal Estrogen Exposure Up-Regulates Estrogen Receptor Expression In The Developing And Adult Rat Prostate Lobes*", Endocrinology 138: 1801-1809, 1997)	
	CC	Shughrue Paul J. et al. "Comparative Distribution Of Estrogen Receptor-α (Er-α) And β (Er-β) mRNA In The Rat Pituitary, Gonad, And Reproductive Tract" Steroids 63: 498-504, 1998, Elsevier Science Inc.	
	CD	Szarka CE et al. "Chemoprevention Of Cancer", Curr Probl Cancer 1994 Jan-Feb; 18(1):6-79.	

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		"Editorial: A New Actor In The Estrogen Receptor Drama-Entre ER-β", Endocrinology Vol. 138, No. 3, (1997).	
	<u> </u>	"When Is Intervention Warranted?", Journal Of Cellular Biochemistry, Supplement 16H:138-139 (1992).	
	CG	Anttila M et al. "Pharmacokinetics Of The Novel Antiestrogenic Agent Toremifene In Subjects With Altered Liver And Kidney Function" Clin Pharmacol Ther 1995 Jun; 57(6):628-35.	
	СН	Colletta Anthony A. et al. "Alternative Mechanisms Of Action Of Anti-Oestrogens" Breast Cancer Research and Treatment 31: 5-9, 1994.	
	CI	Fleton SA "Potential New Antiestrogens For The Treatment Of Breast Cancer", Highlights in Oncology Practice Vol. 15, No. 2, 1997 p. 47-52	
	CJ	Griffiths K. et al. "Further Insights Into Endocrine Disease - Diet and Prostate Disease" An IPHC Teaching Programme.	
	СК	Horton J et al. "Tamoxifen In Advanced Prostate Cancer: An ECOG Pilot Study", Prostate 1988; 12(2):173-7.	
	CL	Kamat AM et al. "Chemoprevention Of Urological Cancer", The Journal Of Urology, Vol. 161. 1748-1760. June 1999, p. 1748-1760.	
	СМ	Kangas L "Development And Biochemical Pharmacology Of Toremifene, An Antiestrogenic Antitumor Drug", Acta Obstet Gynecol Scand 1991; 70(4-5): 399.	
	CN	Kuiper George G. J. M. et al. "Comparison Of The Ligand Binding Specificity And Transcript Tissue Distribution Of Estrogen Receptors α and β", Endocrinology Vol. 138, No. 3, 863-870 (1997).	
	СО	Moon R.C. et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Research 14: 889-894 (1994)	
	CP	Nevalainen M.T. et al. "Estrogen and Prolactin Regulation of Rat Dorsal and Lateral Prostate in Organ Culture", Endocrinology, Vol. 129, No. 2 pages 612-618	
	CQ	Price K. R. et al. "Naturally Occurring Oestrogens in Food - A review", Food Additives and Contaminants, 1985, Vol. 2, No. 2, 73-106.	
	CR	Yu H et al. "Induction Of Prostate Specific Antigen Production By Steroids And Taxoxifen In Breast Cancer Cell Lines", Breast Cancer Res Treat 1994; 32(3)291-300.	

		
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Signature	Cor	nsidered

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Sheet	7	of	10	Attorney Docket Number	P-2769-US9	

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Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	cs	"New Research Approaches In The Prevention And Cure Of Prostate Cancer", American Association For Cancer Research. December 1998	
	СТ	Boehm S et al. "Estrogen Suppression As A Pharmacotherapeutic Strategy In The Medical Treatment Of Benign Prostatic Hyperplasia: Evidence For Its Efficacy From Studies With Mepartricin" Wien Klin Wochenschr 1998 Dec 11; 110(23):817-23.	
	CU	Bonkhoff H et al. "Estrogen Receptor Expression In Prostate Cancer and Premalignant Prosatic Lesions", American Journal of Pathology, Vol. 155, No. 2 August 1999.	
	CV	Buelke-Sam J. et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology And Reproductive And Developmental Testing", Reprod Toxicol 1998 May-June; 12(3):217-21.	
	CW	Cheng E et al. "Endocrinology Of The Prostate", Prostate Diseases, chapter 5- p. 57-71.	
СХ		Dhar JD et al. "Estrogen, Androgen and Antiestrogen Responses In The Accessory Organs Of Male Rats During Different Phases Of Life", Endocr Res 1998 May; 24(2): 159-69.	
	CY	Landstrom M, et al. "Inhibitory Effects Of Soy and Rye Diets On The Development Of Dunning R3327 Prostate Adenocarcinoma in Rats, The Prostate 36: 151-161 (1998).	
	CZ	Strauss L "Genistein Exerts Estrogen-Like Effects In Male Mouse Reproductive Tract", Molecular and Cellular Endocrinology 144 (1998) 83-93, Elsevier Science Ireland Ltd.	
	DA	Treinen KA et al. "An Evaluation Of The Novel Selective Estrogen Receptor Modulator, Idoxifene, For Effects On Reproduction In Rats And Rabbits:, Toxicol Sci 1998 Feb; 41(2):199-207.	
	DB	West Neal B et al. "Estrogen and Progestin Receptors And Aromatase Activity In Rhesus Monkey Prostate" Endocrinology, Vol. L. 123, (1998)	
	DC	Xiaolin Zi et al. "Silibinin Decreases Prostate-Specific Antigen With Cell Growth Inhibition Via G1 Arrest, Leading To Differentiation Of Prostate Carcinoma Cells: Implications For Prostate Cancer Intervention:, Proc. Nsil. Acad. Sci, USA Vol. 96, pp. 7490-7495, June 1999. Medical Sciences.	

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Signature		Considered	

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				Application Number	10/747,686	
INF	ORMA	TION	DISCLOSURE	Filing Date	December 30, 2003	
STA	ATEME	NT B	Y APPLICANT	First Named Inventor	STEINER, Mitchell S.	
			•	Group Art Unit	1615	
((use as ma	ny she	ets as necessary)	Examiner Name	Fubara, Blessing M	
Sheet	8	of	10	Attorney Docket Number	P-2769-US9	

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	DD	Albert David S. et al. "An Overview Of Clinical Cancer Chemoprevention Studies With Emphasis On Positive Phase III Studies" Overivew of Diet Cancer 6928-6975 (1995)					
	DE	Buelke-Sam Judy et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology and Reproductive Development Testing", Reproductive Toxicology Vol. 12, No. 3 pp. 217-221, 1998.					
	DF	Hayes "A Randomized Comparison Of Tamoxifen, Trioxifene And A New Estrogen Antogonist (LY117018) In Rats And Mice" In Life Sciences, 1980, vol. 26, pp. 1453-1458.					
	DG	Hobisch Alfred "Metastatic Lesions From Prostate Cancer Do Not Express Oestrogen And Progesterone Receptors" J. Pathol. 182: 356-361, 1997.					
	DH	Horton John et al. "Tamoxifen In Advanced Prostate Cancer" An ECOG Pilot Study", The Prostate 12: 173-177 (1988).					
	DI	Jordan Craig V. "Antiestrogenic Action of Raloxifene and Tamoxifen: Today and Tomorrow" Journal of National Cancer Institute, Vol. 90, No. 13, July 1, 1998					
	DΊ	Kellof GJ et al "Strategies For Chemoprevention Of Prostate Cancer", Prostate Cancer and Prostate Disease (1988) 5. 107.					
	DK	Kuiper George G. J. M. "Cloning Of A Novel Estrogen Receptor Expressed In Rat Prostate And Ovary", Proc. Natl. Acad. Sci USA Vol. 93, pp. 5925-5930, June 1996 Biochemistry.					
	DL	Kuiper George G. J. M. "Interaction Of Estrogenic Chemicals and Phytoestrogens With Estrogen Receptor β", Endocrinology Vol. 139, No. 10 (1998).					
	DM	Mobbs, B.G. et al "Concentration and Cellular Distribution of Androgen Receptor in Human Prostatic Neoplasia: Can Estrogen Treatment Increase Androgen Receptor Content?" J. Steroid Biochem. Vol. 19, No. 3 pp. 1279-1290, 1983.					
-	DN	Prins Gail S. "Developmental Estrogenization Of The Prostate Gland", Prostate:Basic and Clinical Aspects p. 245-263 (1997).					
	DO	Strom Sara S. et al. "Phytoestrogen Intake and Prostate Cancer: A Case-Control Study Using A New Database", Nutrition and Cancer, 33(1), 20-25. (1999).					
	DP	Warri Anni. M. et al "Apoptosis in Toremifene Induced Growth Inhibition of Human Breast Cancer Cells in Vivo and In Vitro" Journal of National Cancer Institute, Vol. 85, No. 17, September 1, 1993					

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NEW DQ FROM HERE		"GTx begins next phase of clinical trials for prostate cancer." Expert Rev Anticancer Ther. 2001 1(3) 326	
		Bostwick David "Prospective Origins of Prostate Carcinoma" American Cancer Society 1996	
		Bostwick, David G. et al "Reversibility of Prostatic Intraepithelial Neoplasia: Implications for Chemoprevention" Eur. Urol 1999: 35:492-495	
	DT	Boyle Peter et al "Epidemiology of Prostate Cancer Chemoprevention" Eur Urol 1999: 35:370-376	
	DU	Hard, Gordon C. et al. "Major Difference in the Hepatocarcinogenicity and DNA Adduct Forming Ability between Toremifene and Tamoxifen in Female Crl: CD(BR) Rats" Cancer Research 53, 4534-4541, October 1, 1993	
·	DV	Krieg, Michael et al "Androgens and Estrogens: Their Interaction with Stroma and Epithelium of Human Benign Prostatic Hyperplasia and Normal Prostate" J. Steroid Biochem. Vol. 19, No. 1 pp. 155-161, 1983	
	DW	Neubauer, et al (1995) "Raloxifene (LY156758) produces antimetastatic responses and extends survival in the PAIII rat prostatic adencarcinoma model. Prostate 27(4)220-9	
	DX	Nevalainen MT et al "Hormone regulation of human prostate in organ culture" Cancer Res. 1993 Nov 1:53 (21):5199-207	
	DY	Pylkkanen, et al (1996) "Animal models for the preneoplastic lesions of the prostate" Eur. Urol. 30 (2) 243-8	
	DZ	Raghow, et al (2002) "Toremifene prevents prostate cancer in the trangenice admocarinoma of mouse prostate model." Cancer Research 1;62(5) 1370-6.	
,	EA	Steiner, et al (2001) Selective estrogen receptor modulators for the chemoprevention of prostate cancer." Urology 57(4 Suppl 1) 68-72	
	EB	Steiner, et al (2003) "Antiestrogens and selective estrogen receptor modulators reduce prostate cancer risk." World Journal of Urology 21(1) 31-6	
	EC	Zaridze, David G. et al "International Trends in Prostatic Cancer" Int. J. Cancer: 33, 223-230 (1984)	
	ED.	Schneider, et al (1996) "Nonsteroidal antiestrogens and partial estrogens with prostatic tumor inhibiting activity." 112 (3) 258-65	

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	EF	Schneider, et al (1991) "Effect of zindoxifene on experimental prostatic tumors of the rat." J. Cancer Res Clin Oncol. 117 (1) 33-6.			
	EG	Ip MM, et al (1980) "Funtionality of estrogen receptor and tamoxifen treatment of R3327 Dunning rat prostate adenocarcinoma." Cancer Res 40 (7) 2188-93.			
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